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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,419	07/19/2001	Abdul Malik	0152.00396	6244

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EXAMINER	
SODERQUIST, ARLEN	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/763,419	MALIK ET AL.	
	Examiner	Art Unit	
	Arlen Soderquist	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 21-22 and 24-39 rejected under 35 U.S.C. 102(b) as being anticipated by Zeng (newly cited and applied). In the paper Zeng teaches the preparation and characteristics of two new GC stationary phases-dihydroxy crown ether containing polysiloxane. Two new kinds of crown ethers: 3,5-dibutyl-unsymmetry-dibenzo-14-crown-4-dihydroxy (cis-, and trans-) with the OH-terminal silicone oil in different proportion were coated on glass capillary columns, and immobilized by condensation using a coupling agent of alkyltrimethoxysilane. Chromatography characteristics, including column efficiency, polarity, selectivity, phase transition temperature and thermal stability were studied. The columns were compared with PEG-20M in terms of polarity and selectivity. The immobilization and retention mechanisms are also discussed. The paragraph bridging pages 85-86 teaches treating the glass tube to prepare it for the coating solution and coating it with a solution that includes a sol-gel precursor (alkyltrimethoxysilane), a sol-gel reactive organic molecule (the cis- or trans-crown compounds) and a deactivation agent (the OH terminal silicone oil). Figure 2 shows a possible mechanism and structure for the coating that appears to be equivalent to that shown in claim 22. The paragraph bridging pages 88 and 90 teaches the addition of trifluoroacetic acid as a catalyst component on the coating composition (see the sol-gel composition outlined on page 24 of the instant specification).

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 23, 31-32 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeng as applied to claims 21-22 and 24-39 above, and further in view of Hayes (1997, hereinafter called Hayes '97) and Guo (newly applied), Narang (newly cited and applied) or Sumpter. The Hayes '97 reference teaches sol-gel chemistry-based Ucon-coated columns for capillary electrophoresis. A sol-gel chemistry-based novel approach for the preparation of a Ucon-coated fused-silica capillary column in capillary electrophoresis is presented. In this approach the sol-gel process is carried out inside 25 μm I.D. fused-silica capillaries. The sol solution contained appropriate quantities of an alkoxide-based sol-gel precursor, a polymeric coating material (Ucon), a crosslinking reagent, a surface derivatizing reagent (hexamethyldisilizane, deactivating reagent), controlled amounts of water and a catalyst dissolved in a suitable solvent system. The coating procedure involves filling a capillary with the sol solution and allowing the sol-gel process to proceed for an optimum period. Hydrolysis of the alkoxide precursor and polycondensation of the hydrolyzed products with the surface silanol groups and the hydroxy-terminated Ucon molecules lead to the formation of a surface-bonded sol-gel coating on the inner walls of the capillary. The thickness of the coated film can be controlled by varying the reaction time, coating solution composition and experimental conditions. Commercial availability of high purity sol-gel precursors (e.g., TEOS 99.999%), the ease of coating, run-to-run and column-to-column reproducibility, and long column lifetimes make sol-gel coating chemistry very much suitable for being applied in analytical microseparations column technology. Test samples of basic proteins and nucleotides were used to evaluate the column performance. These results show that the sol-gel coating scheme has allowed for the generation of biocompatible surfaces characterized by high separation efficiencies in CE. For different types of solutes, the sol-gel coated Ucon column consistently provided migration time R.S.D. values of the order of 0.5%. The experimental section of Hayes is identical or equivalent to page 22, lines 8-24 of the instant specification. Also figure 1 of Hayes is identical to figure 3 of the instant specification. In the first paragraph of the paper Hayes discusses the problems associated with fused-silica capillary columns cause by the

adsorption of biomolecules with acidic silanol groups on the inner surface of the capillary. The last full paragraph of the left column of page 4 teaches several advantages of the sol-gel technique including the strong adhesion of the coating due to the chemical bond formed. The last paragraph of page 5 teaches the cleaning of the capillary followed by addition of the coating solution. The paragraph bridging the columns of page 6 discusses the factors that are responsible for the adsorption problem. Relative to the silanol groups Hayes teaches that a uniform distribution of the groups is necessary to achieve a uniform coverage of the chemically bonded organic coatings. The same paragraph teaches that untreated fused-silica capillaries are characterized by low concentrations and non-uniform distributions of these groups on the inner surface. This paragraph teaches that there is also the possibility for new silanol groups to be formed through reaction of the surface with atmospheric moisture. Consequently, chemical research into creation of silica surfaces with uniformly distributed silanol groups at their optimum concentration is fundamentally important for the overall development of column technology for capillary electrophoresis and other separation techniques. Important to the instant claims is the statement in this paragraph that a "silica surface with uniformly distributed silanol groups should be very much suited for its further chemical modification using various polymeric and monomeric reagents with functional groups that can react with silanol groups". Also in this paragraph is the statement that these "chemically bonded coatings will ensure effective coverage of the surface and reliably shield the residual silanol groups to prevent their participation in solute adsorption phenomena."

In the paper Sumpter discusses static coating of 5 to 50 μm I.D. capillary columns for open tubular column chromatography. Dichlorofluoromethane, CCl3F, and Me4Si were used in the static coating of small diameter capillary columns (5 to 50 μm I.D.) to obtain highly efficient columns for gas and supercritical fluid chromatography. Capillary columns of 5-, 10-, 25-, and 50-μm I.D. were coated with stationary phase films of SE-33, SE-54, OV-215, 50% octyl, 45% phenoxypolyethyl ether, 50% liquid crystal, 25% biphenyl, 50% pentafluorophenyl, and 50% cyanopropyl polysiloxane stationary phases. Resultant evaluations of these columns in gas chromatography gave ~9000, 66000, 45000, and 19000 plates m^{-1}, respectively, for the different internal diameters. Important parameters affecting coating efficiency are identified and discussed in detail. Page 504 teaches that several preparation methods have been used for open

tubular chromatography columns. Relative to the instant claims is the discussion of the chemical bonding method of coating the tubes. Page 506 teaches treating the columns prior to deactivation by a hydrothermal treatment and a dehydration treatment.

In the paper Guo a stationary phase for open tubular liquid chromatography and electrochromatography using sol-gel technology. An organic-inorganic hybrid material was fabricated by the sol-gel method and cast as a thin glass film onto the inner walls of fused silica capillary columns. The thin film in the capillaries functioned as the stationary phase for reversed phase open tubular liquid chromatography (OTLC) and open tubular electrochromatography (OTEC). The stationary phase provides high surface area and thus an improved phase ratio. Multiple preparation steps are avoided by attaching the stationary phase and increasing the surface area in a single procedure. By adjusting the ratio of the monomeric precursors in the original sol-gel solution, the retentive characteristics of the stationary phase are controlled. This new approach facilitates column preparation for OTLC and OTEC. Capillary columns prepared in this manner showed retention characteristics superior to conventionally prepared ones. The sol-gel-derived stationary phase was shown to be stable under acidic and basic conditions.

In the paper Narang sol-gel-derived fluorinated stationary phase for open tubular electrochromatography. The sol-gel-derived fluorinated column was prepared by hydrolyzing a mixture of tetraethoxysilane (TEOS) and tridecafluoro-1,1,2,2-tetrahydrooctyl-1-triethoxysilane (F13-TEOS) followed by coating a thin film onto the inner walls of a fused-silica capillary. The retention characteristics of the sol-gel-derived fluorinated column are compared with a sol-gel-derived octylhydrocarbonaceous (C8) column. Using the sol-gel-derived fluorinated column, the authors report on the successful separation of six model fluorinated organic compounds which cannot be separated using the C8 column prepared either via sol-gel method or by conventional methods. The authors achieved high efficiencies of 100000-300000 plates/m for the various model fluorinated compounds using the sol-gel-derived fluorinated column. The authors also studied the separation performance of the sol-gel-derived fluorinated column using different TEOS:F13-TEOS ratios and the optimum reaction time before column coating. Optimum selectivity was obtained with a TEOS:F13-TEOS molar ratio of 1:2 reacted for 24 h prior to column coating.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate other deactivation reagents as taught by Hayes '97 or sole-gel reactive organic molecules as taught by Hayes '97, Guo, Narang or Sumpter into the stationary phase of Zeng because of their ability to efficiently coat the tube with functional groups that can react with silanol groups, these chemically bonded coatings will ensure effective coverage of the surface and reliably shield the residual silanol groups to prevent their participation in solute adsorption phenomena to provide effective separations as taught by Hayes '97, Guo, Narang and Sumpter.

5. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. The newly cited and applied Zeng reference clearly anticipates a majority of the instant claims since the mixture applied to the interior of the column is equivalent to that found on page 24 of the instant specification.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The newly cited art is discussed above in relation to forming columns.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose at telephone number is (571) 272-1265. The examiner's schedule is variable between the hours of about 6:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

A general phone number for the organization to which this application is assigned is (571) 272-1700. The fax phone number to file official papers for this application or proceeding is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Arlen Soderquist
Primary Examiner